

### **REMARKS/ARGUMENTS**

Claims 1-29 are pending in the application. Claims 1-5 and 21-29 have been rejected under 35 U.S.C. Section 103(a). Claims 1, 2, and 24 - 29 have been amended. Claims 6 - 20, formerly withdrawn from consideration, have been cancelled without prejudice to the filing of a divisional application. Reconsideration of the claims in view of the amendments and the following remarks is respectfully requested.

#### **Claim Objections**

Claims 1, 2, and 24 - 29 have been objected to for various informalities. The claims have been amended to correct these deficiencies, and the Applicants respectfully request that the objections to the claims be withdrawn.

#### **103 Rejection**

Claims 1 - 4, 21 - 24, 28, and 29 have been rejected under 35 U.S.C. Section 103(a) as unpatentable over Osorio, U.S. Patent 6,341,236 in view of Adkins, U.S. Patent 5,928,272. Claims 5 and 25 - 27 have been rejected as unpatentable over Osorio in view of Adkins, and further in view of Lo, U.S. Patent 5,738,104. Reconsideration of these claims is respectfully requested.

Claim 1, as amended, recites a method for non-invasive detection of a vagus nerve stimulation signal. The method includes the steps of applying external electrodes to a patient in proximity to an implanted vagus nerve stimulator. A detected vagus nerve signal is detected, amplified, filtered, and then prolonged to allow sampling of the vagus nerve stimulation signal and to trigger sampling of at least one other physiological signal to allow for monitoring the effect of the vagus nerve stimulation on the at least one other physiological signal. The present invention, therefore, provides a non-invasive method for determining when the vagus nerve has been stimulated, and for triggering the monitoring of

other physiological signals based on the vagus nerve stimulation, thereby allowing for monitoring of the effects of vagus nerve stimulation without the need to implant additional devices into a patient. The method of the present invention, moreover, can be used to monitor the effectiveness of any type of vagus nerve stimulation device.

The prior art Osorio reference discloses an automatic neurostimulation device including a signal generator 20 for stimulating the vagus nerve and an associated sensor 15 for monitoring the heart rate. Data derived from the heart rate sensor 15 is monitored to determine whether vagus nerve stimulation is adversely affecting the heart. In a particular embodiment discussed at column 11 line 18 - column 12 line 3, a pacemaker is equipped with a signal processing algorithm for detecting VNS-induced artifacts in the EKG signal and controlling the heart to maintain the heart within desired conditions during vagus nerve stimulation.

Adkins discloses an implanted device for controlling seizures in an epileptic patient. Referring to Fig. 1, the device includes a generator 25 equipped with sensing electrodes for measuring electrical impulses indicating cardiac activity, and an array of stimulating electrodes 15 implanted adjacent the vagus nerve for stimulating the vagus nerve. An electrical signal 47 indicative of cardiac activity (such as an EKG or ECG signal) is monitored (see column 6, lines 54 through 58; column 9 lines 7 - 11) to determine whether a time rate of change of the patient's heart rate indicates that a seizure is imminent, and applies stimulation to the vagus nerve accordingly.

Osorio, therefore, discloses an implanted pacemaker device that monitors an EKG signal, processes this signal to determine when a vagus nerve stimulation is detected, and adjusts stimulation of the heart based on the vagus nerve stimulation. Osorio neither teaches nor suggests any method for monitoring a vagus nerve stimulation signal through external electrodes, or for triggering monitoring of other physiological parameters. Adkins, similarly,

discloses an implanted monitoring device that is intended to monitor and adjust cardiac activity. Adkins does not teach any method of monitoring a vagus nerve stimulation signal, or any method of using vagus nerve stimulation signals to trigger monitoring of other physiological parameters.

Neither reference, therefore, discloses a method for monitoring a vagus nerve stimulation that uses external electrodes as recited in claim 1, as amended. Neither reference teaches or suggests prolonging a detected vagus nerve stimulation signal and using the signal to trigger monitoring of other physiological parameters.

In view of these distinctions, these references cannot be combined to provide the invention as recited in claim 1, as amended, or associated dependent claims 2 - 5 and 21 - 29. Therefore, the Applicants respectfully request that the rejection of claims 1 - 5 and 21 - 29 under 35 U.S.C. Section 103 be withdrawn.

The Commissioner is authorized to charge any fees under 37 CFR § 1.17 that may be due on this application to Deposit Account 17-0055. The Commissioner is also authorized to treat this amendment and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

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